Citation:

Aiello AE, Larson EL, Levy SB. Consumer antibacterial soaps: effective or just risky? *Clinical Infectious Diseases* 2007; 45:S137–47.

PubMed ID: 17683018

Study Design:

Systematic Review

Class:

M - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

NEUTRAL: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

- To identify and summarize the studies examining the efficacy of triclosan by reviewing research that has examined the effectiveness of these consumer antiseptic soaps at reducing the incidence of infectious illnesses in the community setting and bacterial counts on the skin.
- To identify and summarize the literature that examines whether there is a potential risk associated with use of hygiene products containing triclosan in relation to emergence of microbes that are less susceptible to triclosan and/or resistant to clinically used antibiotics.
- To weigh the evidence regarding the risks and benefits and conclude with recommendations for further research and for examining the implications of the current data on regulation of consumer products containing triclosan.

Inclusion Criteria:

- Articles assessing mechanisms of cross-resistance, using serial culture adaptation methodologies and/or genetic manipulation of the bacterial molecular target site of triclosan
- Articles assessing levels of susceptibility to triclosan among bacterial isolates obtained from humans in the community setting
- Articles examining the statistical association between in-use exposure to triclosan and reduced susceptibility to triclosan and/or antibiotic resistance among humans living in the community setting

Exclusion Criteria:

- Articles were excluded if the setting was a health care facility, such as a hospital or residential nursing home, or if the study subjects were health care workers
- Studies in which triclosan was combined with other antiseptic ingredients, such as alcohol or iodine, were excluded
- Articles that focused on triclosan in dentifrice were excluded, because the introduction of

triclosan in dentifrice was relatively recent (1997), compared with its introduction in topical antiseptics (1960s)

Description of Study Protocol:

Recruitment

- PubMed database was searched for English-language articles published during the period January 1980–July 2006, using keyword combinations for each search strategy
- The search results were scanned for research articles and systematic reviews
- In addition, the reference lists in retrieved review papers were searched for related articles

Design: Systematic Review

Blinding used (if applicable): not applicable

Intervention (if applicable): not applicable

Statistical Analysis:

- The strengths and limitations of the studies were assessed by considering methods related to design and conduct, such as sample size and masking of treatment from study participants.

Data Collection Summary:

Timing of Measurements: not applicable

Dependent Variables

- Infectious illness symptoms
- Bacterial growth on skin
- Reduced susceptibility to triclosan and emergence of antibiotic resistance

Independent Variables

- Use of triclosan

Control Variables

Description of Actual Data Sample:

Initial N:

- The PubMed search identified 1793 citations.
- Number of articles screened: not described.

Attrition (final N): A total of 27 studies that examined either the effectiveness of triclosan or the risks of antibiotic resistance associated with exposure to triclosan met the eligibility criteria. The number of excluded studies and reasons were not described.

Age: not applicable

Ethnicity: not applicable

Other relevant demographics

Anthropometrics

Location: International studies

Summary of Results:

Key Findings:

- Soaps containing triclosan within the range of concentrations commonly used in the community setting (0.1% to 0.45% weight/volume) were no more effective than plain soap at preventing infectious illness symptoms and reducing bacterial levels on hands
- Several laboratory studies demonstrated evidence of triclosan-adapted cross-resistance to antibiotics among different species of bacteria

I. Studies comparing the efficacy of antibacterial soap containing triclosan (Ts) with that of plain soap -

- **Infectious illness studies**
  - **Study characteristics:** 4 community-based randomized intervention studies. Three of these studies were conducted in Pakistan, and 1 was conducted in an urban setting in the United States. The study sample sizes ranged from 162 to 600 household units, and all households were required to include a child ≤4 years of age. Interventions included household member use of consumer-available bar soap containing 1.2% triclocarban (wt/vol) or liquid hand soap containing 0.2% triclosan (wt/vol) over a 1-year period. The outcomes recorded infectious illness symptoms such as cough, fever, diarrhea, and skin infections. None of these studies included the collection of clinical samples for laboratory identification of the etiologic agent associated with illness symptoms.
  - **Summary of findings:** All 4 studies showed no significant reduction in illness symptoms among household members associated with the use of the biocide-containing soap versus plain soap.
- **Microbiological studies**
  - **Study characteristics:** 9 studies that examined the effectiveness of soap containing triclosan versus plain soap in reducing bacterial levels on the hands. The majority of the microbiological effectiveness studies (n=8) were conducted in a controlled laboratory setting, and 1 was conducted under natural conditions in the household setting. Study sample sizes ranged from 10 to 238 subjects, and study subjects were characterized as nonclinical volunteers. Slightly fewer than half (4/9) of the studies mentioned the use of randomization procedures, and only 22% reported masking of study treatments. Most of the studies examined the normal skin flora as the outcome, but 2 of the 9 studies used artificial contamination procedures, by inoculating the skin of volunteers with *S. marcescens*. Approximately half (5/9) of the microbiological studies compared soap with at least 1.0% triclosan (wt/vol) versus plain soap, whereas the others utilized a concentration of ≤0.3% triclosan (wt/vol) in the comparison.
  - **Summary of findings:** All but 1 of the 5 studies utilized soap with a relatively high concentration of triclosan, ≤1.0%, and 2 of the 5 studies reported a significant reduction only after multiple hand washes, over multiple hand-washing episodes, or after washing for 30 s. Only 1 study assessing triclosan at a concentration of 0.3%

wt/vol (a concentration closer to the 0.1%–0.45% wt/vol found in many consumer antibacterial soaps) reported a significant reduction in bacterial counts, and this reduction was observed only after 18 hand washes per day, for 30 s each, over 5 consecutive days.

II. Triclosan (Ts) adaptation and antibiotic cross-resistance studies -

- **Study characteristics:** 11 studies laboratory studies assessing the influence of triclosan exposure on the emergence of triclosan-tolerant species and cross-resistance to clinical antibiotics. A range of bacteria was examined, including gram-negative and gram-positive species; commonly studied species included *Escherichia coli*, *Staphylococcus aureus*, and *Salmonella enterica*. Seven of the 11 studies demonstrated cross-resistance to ≥1 antibiotic for at least 1 of the bacterial species examined. Commonly assessed antibiotics included isoniazid, ciprofloxacin, erythromycin, tetracycline, chloramphenicol, ampicillin, and methicillin.
- **Summary of findings:** Three of 11 studies reported an increase in MICs to triclosan among bacterial species but did not demonstrate cross-resistance to clinically used antibiotics. One study examining*E. coli* reported no evidence of increased tolerance to triclosan or cross-resistance to antibiotics. Given the variety of bacterial species and antibiotics tested across studies, it was not possible to assess whether a consistent pattern of cross-resistance for specific organism/antibiotic combinations existed.

III. Community-level studies of the relationship between exposure to triclosan in home hygiene products and antibiotic resistance -

- 3 studies that examined the emergence of antibiotic resistance associated with use of triclosan in the community setting.The first study included a convenience sample of 60 households divided into those that reported using ≥1 antibacterial hygiene products and those that reported no use of antibacterial hygiene products. Bacteria were isolated from the hands of household members and their home environments. There was no information on the concentration or prevalence of triclosan-containing products among the reported antibacterial-user households. Although the sample size was not sufficient to make statistical comparisons, the authors of the study still concluded that there was no association between use of antibacterial products and the presence of antibiotic-resistant species among household members and their environment.
- The next 2 studies were derived from a randomized and masked intervention trial of 238 households allocated to using either 0.2% triclosan–containing liquid hand soap or plain soap. Bacterial samples were obtained from the hands of household members at baseline and after 1 year of using the assigned hand hygiene product. Neither of these studies demonstrated the emergence of antibiotic resistance associated with use, over a 1-year period, of the liquid hand soap containing 0.2% triclosan compared with plain soap. The authors did note that several species, such as P. aeruginosa and some coagulase-negative staphylococcal species, demonstrated unexpectedly high MICs to triclosan at both baseline and the end of the year.

Author Conclusion:

The available data do not support the effectiveness of triclosan for reducing infectious disease symptoms or bacterial counts on the hands when used at the concentrations commonly found in consumer antiseptic hand soaps. The effectiveness was similar to that of plain soap in the majority of studies, and a difference in the reduction of bacterial levels on the hands was generally observed

only after longer hand washes with soap containing relatively high concentrations of triclosan (i.e., ≥1.0% wt/vol).

Regarding the risks associated with triclosan, we identified several studies that supported a relationship between exposure of bacteria to triclosan in the laboratory and increased MICs to clinically utilized antibiotics. In contrast, research conducted at the population level showed little evidence of cross-resistance with antibiotics associated with household use of hygiene products containing triclosan.

The lack of an additional health benefit associated with the use of triclosan-containing consumer soaps over regular soap, coupled with laboratory data demonstrating a potential risk of selecting for drug resistance, warrants further evaluation by governmental regulators regarding antibacterial product claims and advertising.

Reviewer Comments:

Limitations:

- *Screening of the full-text articles, and the number of excluded studies and reasons were not described.*
- *Data extrraction process was not described.*
- *Methodologic quality of included studies were not assessed.*

Research Design and Implementation Criteria Checklist: Review Articles

Relevance Questions		
1.	Will the answer if true, have a direct bearing on the health of patients?	Yes
2.	Is the outcome or topic something that patients/clients/population groups would care about?	Yes
3.	Is the problem addressed in the review one that is relevant to nutrition or dietetics practice?	Yes
4.	Will the information, if true, require a change in practice?	Yes

Validity Questions		
1.	Was the question for the review clearly focused and appropriate?	Yes
2.	Was the search strategy used to locate relevant studies comprehensive? Were the databases searched and the search termsused described?	Yes
3.	Were explicit methods used to select studies to include in the review? Were inclusion/exclusion criteria specified and appropriate? Were selection methods unbiased?	No
4.	Was there an appraisal of the quality and validity of studies included in the review? Were appraisal methods specified, appropriate, and reproducible?	No
5.	Were specific treatments/interventions/exposures described? Were treatments similar enough to be combined?	Yes

6.	Was the outcome of interest clearly indicated? Were other potential harms and benefits considered?	Yes
7.	Were processes for data abstraction, synthesis, and analysis described? Were they applied consistently across studies and groups? Was there appropriate use of qualitative and/or quantitative synthesis? Was variation in findings among studies analyzed? Were heterogeneity issued considered? If data from studies were aggregated for meta-analysis, was the procedure described?	No
8.	Are the results clearly presented in narrative and/or quantitative terms? If summary statistics are used, are levels of significance and/or confidence intervals included?	Yes
9.	Are conclusions supported by results with biases and limitations taken into consideration? Are limitations of the review identified and discussed?	Yes
10.	Was bias due to the review's funding or sponsorship unlikely?	Yes